IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

B.M., Plaintiff , vs. FUJIFILM IRVINE SCIENTIFIC, INC , Defendant.	C.A. No.: 6:23-cv-2541-JD **COMPLAINT** **JURY TRIAL DEMANDED**

NOW COMES, through undersigned counsel, comes Plaintiff B.M., and bring this Complaint against Defendant FujiFilm Irvine Scientific, Inc. ("Irvine Scientific" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. Fertility doctors, laboratories, clinics, and hospitals trusted Defendant Irvine Scientific to provide a safe and thoroughly tested oil to preserve and protect their patients' embryos.

2. Defendant, however, manufactured, marketed, distributed, and sold a toxic embryo oil. This toxic embryo oil destroyed or negatively impacted the quality of human embryos, including those created for Plaintiffs.

3. Plaintiffs seek damages for the loss of their precious embryos and to hold Defendant responsible for failing to carefully manufacture and adequately test a product it knew would be used in delicate and exacting assisted reproductive technology procedures involving human embryos.

PARTIES

4. Plaintiff BM is a resident of Greenville South Carolina.

5. Given the sensitive nature of the claims and disclosure of medical information, Plaintiffs are using initials in this litigation to protect their privacy. If required by the Court, Plaintiff will seek permission to proceed with use of these initials.

6. Defendant Irvine Scientific is a corporation organized under the laws of the State of California with its principal place of business and corporate headquarters in Santa Ana, California.

7. Defendant Irvine Scientific purports to be a "worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices… The company provides unrivalled service and quality to scientists working in … assisted reproductive technology…"

8. Among the products Defendant developed, manufactured, marketed, promoted, distributed, and sold was a sterile oil product specifically designed to create an ideal medium for the culturing and storage of human embryos.

9. Upon information and belief, Defendant knowingly markets, distributes, and sells its "Fujifilm" branded products, including its embryo oil, in the State of South Carolina.

10. Upon information and belief, Defendant's activities include sending fertility doctors, scientists, laboratories, clinics, and/or hospitals in South Carolina information about the use and benefits of its fertility products, including, but not limited to, the "Fujifilm" branded oil at issue here.

11. Upon information and belief, Defendant knew that its fertility products, including, but not limited to, the "FujiFilm" branded oil at issue here, were being sold, distributed, and used by fertility doctors, scientists, laboratories, clinics, and/or hospitals in South Carolina.

JURISDICTION AND VENUE

12. Subject matter jurisdiction in this matter is proper because the amount in controversy, exclusive of interest and costs, exceeds Seventy-five Thousand Dollars ($75,000) and the parties are citizens of different states, both as required by 28 U.S.C. § 1332(a).

13. Venue of this matter is proper in the United States District Court for the District of South Carolina pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim set forth herein occurred in this judicial district. Specifically, Defendant's embryo oil was marketed, distributed, and sold to Piedmont Reproductive Endocrinology Group (PREG) in Greenville South Carolina where it destroyed Plaintiffs' embryos.

FACTUAL BACKGROUND

14. The global assisted reproductive technology market has been valued at $25.7 billion dollars in 2022 and is growing steadily.

15. Defendant Irvine Scientific is one of the world's largest suppliers of assisted reproduction technology products. Specifically, Defendant focuses on producing and selling an array of media used by doctors, scientists, laboratories, clinics, and/or hospitals working in the assisted reproductive technology field. These include gamete processing media; fertilization and embryo culture media; sperm preparation media; vitrification media; micromanipulation and ICSI media; protein supplements and oils; and other supplies used in assisted reproduction medicine.

16. Most of Defendant's products are branded "Fujifilm" and "IrvineScientific" to convey to the users of its products that the company stands behind the product; that the products have been meticulously researched, tested, and manufactured; and that the products are reliable and safe for their intended use.

17. Among the products Defendant developed, marketed, manufactured, distributed, and sold is a sterile mineral oil for use with embryos.

18. Defendant describes this product as follows:

> Oil for Embryo Culture is a sterile light mineral oil intended for use as an overlay when culturing in reduced volumes of media to prevent evaporation, and to protect the media from changes in osmolality and pH.

19. The product is designated by Defendant as "Model # 9305."

20. The oil is sold in 100 and 500 ml containers.

21. The packaging of Defendant's embryo oil in the 100 ml container is depicted below:

22. By far, the most common type of assisted reproductive technology is in vitro fertilization ("IVF"), a process where eggs are extracted from a woman and fertilized in a laboratory with sperm to create an embryo. The embryo is then stored until transplanted into a uterus.

23. The process requires an array of advanced technology and medical knowhow. For patients, the process often involves taking medication, transvaginal ultrasounds, blood tests, hormone injections, a surgical procedure to remove the eggs, sperm collection, and insemination of the collected eggs in a lab.

24. After fertilization, the embryo is grown and sometimes stored for a period of time before being implanted into the hopeful mother's uterus.

25. Defendant's embryo oil is used during this storage period to prevent evaporation, insulate against changes in pH, and otherwise protect the valuable embryos.

26. According to Defendant, its oil is "ideal for use in micro-drop cell cultures, preventing evaporation of the aqueous phase, and providing an insulation against rapid changes in pH when the atmospheric (i.e., % CO_2) conditions change."

27. Defendant differentiates its embryo oil from other products based on quality and safety. For example, Defendant writes that "Irvine Scientific's light mineral oil for embryo culture is used as an overlay to cover small volumes of media to prevent evaporation and changes in pH. Our oil is sterile filtered and aseptically processed to provide the highest quality oil available."

28. Defendant represented that its oil products were properly tested, and carefully manufactured to prevent toxicity to embryos.

29. Defendant, however, knew or should have known that its testing and manufacturing process was not adequate to prevent toxicity to human embryos.

30. Upon information and belief Defendant produced at least four lots of its mineral oil that were toxic to embryos and therefore unfit for the use that the product was intended. After investigation Defendant concluded three of these lots were found to have "toxic" elements. The fourth lot was derived from the same lot of raw material.

31. This toxicity was discovered by fertility clinics who observed a spike in the failure rates of new human embryos.

32. At least one of these fertility clinics conducted its own study of the oil using mice. This study confirmed that the oil produced, distributed, and sold by Defendant was toxic to human embryos.

33. On January 16, 2023, Defendant issued an "Urgent Field Safety Notice (product removal)" notifying the doctors, clinics, laboratories, and hospitals who had purchased its product that it should not be used and was effectively being recalled.

34. This safety notice identified four lots that were toxic. The recalled toxic products were identified as follows: "Oil for Embryo Culture, Catalog #9305, Lots 0000011351, 0000011367, 0000015999, 0000016000."

35. Defendant admitted it had received complaints regarding oil from the identified lots, including the destruction of human embryos from contact with its oil.

36. Through no fault of their own, Plaintiffs' embryos were destroyed by Defendant's toxic oil.

37. Long before their marriage, Plaintiffs both dreamed of becoming parents. Soon after their marriage, the couple attempted to have children naturally but were unsuccessful.

38. The Plaintiff sought treatment for infertility at the Piedmont Reproductive Endocrinology Group that included undergoing an In Vitro Fertilization process that included extensive medication to stimulate oocyte production, retrieval of the eggs, retrieval of her husband's sperm, in vitro penetration of the retrieved oocytes by sperm, and embryo production.

39. All of this careful planning and treatment resulted in the creation of embryos.

40. Those embryos were stored using Defendant's toxic and later-recalled oil, resulting in the destruction of all Plaintiffs' embryos.

41. Plaintiffs were informed that their embryos came into contact with the oil from the recalled lots; that the embryos were destroyed; and that the oil was tested and confirmed to be toxic.

42. As a result of Defendant's toxic product, Plaintiffs suffered the loss of their embryos, suffered, and continue to suffer great emotional harm, and must undergo painful, stressful, and lengthy medical procedures. Their chances of conceiving children with their own genetic material have also been irreparably reduced.

FOR A FIRST CAUSE OF ACTION

Breach of Warranty

43. Plaintiffs incorporate the above allegations by reference.

44. Defendant developed, designed, manufactured, distributed, marketed, promoted, and sold embryo oil.

45. Defendant intended that this oil be used in the manner that Plaintiffs and their medical providers in fact used it. Plaintiffs, their doctors, clinic, and hospital used Defendant's product precisely as intended.

46. Defendants expressly and impliedly warranted that its oil was safe and non-toxic for use with embryos; was of merchantable quality; met or exceeded the quality of other comparable oils; and was adequately tested and fit for its intended use.

47. Defendants breached these express and implied warranties with respect to its embryo oil by, among other things, inadequately testing the oil and selling oil that was toxic to embryos.

48. Defendants breached these express and implied warranties when it developed, designed, manufactured, distributed, and sold embryo oil that was unfit and unreasonably dangerous for the ordinary purposes for which this oil is used. Specifically, the oil was intended to be used to preserve and protect embryos and Defendant's oil was in fact toxic to those embryos.

49. At the time the oil left Defendant's possession, the oil had been defectively manufactured such that it differed substantially from Defendant's intended product specifications. Rather than safe to use with human embryos, Defendant's oil was toxic to them.

50. As a direct result of Defendant's breach of its express warranties and implied warranties, including but not limited to the implied warranty of merchantability and the implied warranty for a particular purpose under South Carolina Code § 15-73-10, Plaintiffs suffered the harms and losses set forth above.

FOR A SECOND CAUSE OF ACTION

Negligent Manufacture, Design, and Warning

51. Plaintiffs incorporate the above allegations by reference.

52. Defendant owed a duty to the fertility doctors, clinics, hospitals, and their patients to use reasonable care in the production of its embryo oil. This included a responsibility to

adequately assess and test all raw materials for any signs of toxicity that might be used in the production of the final product.

53. Defendant knew its product would be used in highly specialized medical procedures involving sensitive cellular material, specifically including embryos. Defendant knew that if their product was toxic to a developing embryo that it could cause the death of a human being.

54. Responsible and reasonable manufacturers of medical-grade embryo oil will rigorously inspect; monitor; and test its manufacturing process and final product to ensure its safety. This includes careful inspection and maintenance of safety standards regarding raw material acquisition and production.

55. Defendant breached this duty by failing to design, manufacture, monitor, inspect and/or test its oil products and their component raw materials to ensure that they were non-toxic and free of contamination.

56. Defendants further provided no warning to Plaintiffs or their doctors including the physicians at PREG regarding the toxicity or risks of toxicity of the embryo oil.

57. The Defendants were negligent in their failure to warn Plaintiffs and their doctor regarding the toxicity of the embryo oil and Defendant knew or should have known about at the time it was used with Plaintiffs' embryos and these negligent acts or omissions caused the Plaintiffs' harms and losses as set forth above.

58. Upon belief there was a delay in the Defendants failure to warn their infertility clinic customers including PREG regarding the potential for toxicity in the Defendant's oil product and that this delay caused an even increased number of embryo's to be injured.

FOR A THIRD CAUSE OF ACTION

Wrongful Death

59. South Carolina law identifies life as beginning at conception. B.M.'s unborn implanted embryo was negatively affected by the Defendant's product causing the embryo to not develop properly ultimately causing death of the embryo. Section 1-1-330. (A) The right to life for each born and preborn human being vests at fertilization.

60. That Plaintiff further brings this Wrongful Death Action for the benefit of themselves in accordance with S.C. Code Ann. § 15-51-10, et seq.

61. As a direct result of the actionable conduct of Defendants, B.M.'s unborn implanted embryo met their untimely death.

62. Plaintiffs have experienced great mental anguish, suffering, grief, sorrow, bereavement, and loss of society, advice, companionship, protection, and pecuniary benefit from the loss of unborn implanted embryos.

63. Plaintiff is informed and believes pursuant to the South Carolina Wrongful Death Act, it is entitled to judgment against Defendants for an award of actual and/or punitive damages in an amount to be determined by the trier of fact and for any additional relief the court deems just and proper.

PRAYER FOR RELEIF

WHEREFORE, the Plaintiff pray for judgment against the Defendant as follows:

A. For an award of compensatory damages, including damages against Defendants for medical and hospital expenses, pain and suffering, mental anguish, disability, and other damages according to proof at trial in excess of Seventy-Five Thousand Dollars ($75,000.00);

B. For reasonable attorney fees and costs;

C. For punitive damages to be awarded if the Plaintiff proves by clear and convincing evidence that the Defendant acted recklessly or willfully in causing harm.

D. For pre-judgment interest;

E. That the Court award Plaintiff the opportunity to amend or modify the provisions of this complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and

F. For such further and other relief this Court deems just and equitable.

PLAINTIFFS DEMAND A TRIAL BY JURY.

Dated: June 2, 2023

Respectfully submitted,

/s/ T. Ryan Langley
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